CLINICAL PRACTICE

ALERT

June 2006

Family PACT
Planning • Access • Care • Treatment
OFFICE OF FAMILY PLANNING
CALIFORNIA DEPARTMENT OF HEALTH SERVICES

MANAGEMENT OF ABNORMAL PAP SMEARS

Invasive cervical cancer is a preventable disease in a large majority of women, as long as preinvasive cervical lesions are effectively detected and treated . The Family PACT Program has adopted the guidelines of the American Society for Colposcopy and Cervical Pathology (ASCCP), which are included with this Clinical Practice Alert.

KEY POINTS

- **The purpose of cervical cancer screening is the detection and treatment of high-grade squamous epithelial lesions (CIN 2/3), adenocarcinoma precursors, and cervical cancers.**
- **Women with biopsy-proven CIN 1 should be observed carefully and treated only if the lesion progresses to CIN 2 or worse, is persistent for one year or more, or if the woman insists upon early treatment.**
- **In addition to their use in triage of atypical squamous cells of undetermined significance (ASC-US), human papillomavirus (HPV) DNA tests may be used in specified follow-up protocols (see attached Family PACT Guidelines).**
- **An office-based tracking system should be used to ensure that women with abnormal Papanicolaou (Pap) smear findings have been notified of their results and that those who are being followed are reminded of the need for return visits, tests, and procedures.**

QUESTIONS AND ANSWERS

Are there preferred approaches to managing ASC-US or low-grade squamous intraepithelial lesions (LSIL) in adolescents (women under 21 years old)?

- Adolescents with results of ASC-US or LSIL are better served with the repeat cytology strategy, since HPV infections are likely to be transient and will resolve quickly. If this strategy is implemented, "reflex HPV test for ASC-US" should ***not*** be ordered when submitting the cervical cytology request to the laboratory.
- If reflex HPV testing is performed, the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin states that as an alternative to colposcopy, an adolescent with an ASC-US result and positive (reflex) HPV test may be monitored with cytology at 6 and 12 months **or** a single HPV test at 12 months.

Why aren't all women with LSIL treated with cryotherapy or Loop Electrosurgical Excision Procedure (LEEP)?

Since about 85 percent of women with biopsy proven CIN 1 will have spontaneous resolution of their lesion, the preferred management approach is observation. If the CIN 1 lesion persists longer than one year, the patient may elect either ongoing observation or treatment. Any time that the lesion progresses to CIN 2 or worse, it should be treated.

What are the indications for colposcopy?

- Pap smear showing ASC-H, HSIL or suspicion of cancer.
- Pap smear showing LSIL, unless in an adolescent or post-menopausal woman* (see attached guidelines).
- Pap smear showing atypical glandular cells (AGC), other than AGC-atypical endometrial cells.
- Pap smear showing ASC-US in the following circumstances:
  - Women who are unlikely or unwilling to return for frequent follow-up.
  - Women not entering HPV testing or repeat cytology management pathways.
  - Repeat Pap smear with ASC-US or worse performed during observation period.
  - High-risk HPV DNA present at initial or subsequent testing (except adolescents as noted above).
- Cervical leukoplakia (visible white lesion) or other unexplained cervical lesion regardless of Pap smear result.
- Unexplained or persistent cervical bleeding regardless of Pap smear result.

Why doesn't Family PACT pay for LEEP cone or "cold knife" cone biopsies?

Family PACT is a limited benefit family planning and sexually transmitted infection (STI) program. When a woman does not have other coverage, the California *Breast and Cervical Cancer Treatment Program* (BCCTP) may provide additional benefits. Family PACT providers can easily certify and enroll clients in the BCCTP via an internet application.

ADDITIONAL RESOURCES FOR TREATMENT OF CERVICAL ABNORMALITIES

- Breast and Cervical Cancer Treatment Program (BCCTP). Access at: **www.medi-cal.ca.gov** or call (800) 824-0088.

* Women not at risk for pregnancy are ineligible for Family PACT but may be eligible for services through BCCTP.

MANAGEMENT OF ABNORMAL PAP SMEARS (cont.)

Application of Family PACT STANDARDS

Family PACT services include family planning methods, STI detection and management, and selected related reproductive health conditions. The detection and management of pre-cancerous and cancerous lesions of the cervix are considered to be part of the latter category.

1. **Informed Consent**
   - Clients shall be advised of the availability of cervical cancer screening, diagnostic, and limited treatment services.
   - Clients should be informed of the recommended cervical cancer screening interval that applies to her individual circumstance.
   - The consent process for cervical cancer screening, diagnostic, and treatment services shall be provided in a language understood by the client and supplemented with written materials.
2. **Access to Care**
   - Pap smears shall be provided without cost to Family PACT clients at all clinical service sites.
   - Diagnostic and limited treatment services for abnormal Pap smears are available under Family PACT, although each provider may determine whether these services will be provided on-site or by referral.
   - Referral resources for medical and psychosocial services beyond the scope of Family PACT, including treatment for cervical conditions, shall be made available to clients. The *BCCTP* offers seamless service delivery to clients with high grade lesions and cervical cancer. Services not listed in the Family PACT *Policy, Procedures, and Billing Instructions* (PPBI) are not reimbursable by the program.
   - Family PACT providers that have completed a Medi-Cal POS Network/Internet agreement can access the BBCTP Enrollment Application at: www.medi-cal.ca.gov, using the BCCTP link, their Medi-Cal provider number, and PIN to certify and enroll clients needing services beyond the scope of Family PACT.
3. **Availability of Covered Services**
   - At this time, Family PACT Program benefits include a routine Pap smear as often as once a year, although clients may choose to have Pap smears less frequently once informed of the guideline.
   - Screening for cervical abnormalities as listed in the PPBI shall be made available to clients as a condition of delivering services under Family PACT.
   - Clients with cervical abnormalities may receive diagnostic and limited treatment services as defined in the PPBI on-site or through referral.
4. **Scope of Clinical and Preventive Services**
   - Clinicians delivering services under Family PACT shall have professional knowledge and skills about medical practice standards pertaining to cervical cancer screening, management of abnormal results, and treatment.
   - Cervical cancer screening is **NOT** required prior to the provision of contraception.
   - The treatment of cervical cytologic abnormalities should be consistent with the *American Society for Colposcopy and Cervical Pathology, Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities.*
   - Providers should have a tracking system to ensure that all Pap smear results are evaluated, women with abnormalities are notified, and those who are observed are reminded of their need for follow-up.
   - Documentation shall include clinical findings and justification for services in the medical record.
5. **Education and Counseling Services**
   - Clients shall receive education on protecting their reproductive health and plans for future pregnancy. Individual education and counseling should be provided for all women to inform them of Pap smear periodicity and the significance and management of abnormal Pap smears.

PROGRAM POLICY

This alert provides an interpretation of the Family PACT Standards for management of abnormal Pap smear results. Providers should refer to the Family PACT *PPBI* for the complete text of the Family PACT Standards, official administrative practices and billing information. For the purposes of this and other Family PACT Clinical Practice Alerts, the term “shall” indicates a program requirement; the term “should” is advisory and not required.

REFERENCES

1. Wright TC, Cox JT, et al. 2001 Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities. JAMA 2002; 287:2120-29. Access at: http://www.asccp.org/consensus/cytological.shtml.
2. Wright TC, Cox JT, et al. 2001 Consensus Guidelines for the Management of Women with Cervical Intraepithelial Neoplasia. Am J Obstet Gynecol 2003; 189:295-304. Access at: http://www.asccp.org/consensus/histological.shtml.
3. American College of Obstetricians and Gynecologists, ACOG Practice Bulletin: Management of Abnormal Cervical Cytology and Histology. Obstet Gynecol 2005; 106:645-64.
4. ACOG Committee Opinion. Evaluation and Management of Abnormal Cervical Cytology and Histology in the Adolescent. Obstet Gynecol 2006; 107:963-68.

Family PACT Abnormal Pap Smear Guidelines

Pap Smear Finding	Action
Specimen adequacy	
Unsatisfactory for evaluation	• Repeat cytology in 4-12 weeks
Satisfactory, negative for SIL, but limited by…few (scant) endocervical cells	• Repeat cytology no earlier than 4 weeks if patient has had an abnormal cytology within the last 3 years or is immunocompromised • Otherwise, repeat cytology in 1 year; then if normal, at scheduled interval • If practice-wide rate is ≥15 percent, discuss remediation with cytopathologist
Organisms	
Trichomonas vaginalis	• If recently treated, no further evaluation is necessary • If not, notify patient and offer *either* presumptive treatment or confirmatory testing • Finding may indicate presence of other sexually transmitted infections (STI) • Unless unsatisfactory, repeat cytology at scheduled screening interval
Fungal organisms morphologically consistent with *Candida* spp.	• Usually due to asymptomatic Candidal colonization • No action is necessary • Patient notification is optional • Unless unsatisfactory, repeat cytology at scheduled screening interval
Shift in flora suggestive of bacterial vaginosis (BV)	• Poor correlation with clinical diagnosis of BV • If recently treated, no further evaluation is necessary • If not, patient notification is optional. If notified, offer confirmatory examination and testing for BV • Repeat cytology at scheduled screening interval
Bacteria consistent with *Actinomyces*	• In IUC user, this finding is rarely associated with pelvic actinomycosis • To evaluate, perform pelvic exam or refer for gynecologic consultation • If negative pelvic exam, management is controversial. IUC removal is not required and there is no evidence of benefit of antibiotic therapy • If continued IUC use, repeat cytology annually

Cellular changes consistent with *herpes simplex* virus (HSV)	• Strongly suggestive of herpes simplex viral shedding
	• If herpes diagnosis is in medical record, patient notification is optional
	  • If not, notify patient of result. Direct tests for herpes virus (culture, DFA) are not indicated
	  • If the patient requests confirmation, a positive HSV type-specific serology will confirm prior infection (not a Family PACT benefit)
	• Finding may indicate presence of other STIs
	• Repeat cytology at scheduled screening interval

Other non-neoplastic findings	

Reactive changes associated with (severe) inflammation	• May be due to gonorrhea (GC), chlamydia (Ct), trichomonas, viruses, irritants, (very rarely) cancer
	• If recent GC, Ct tests were negative, further infection evaluation is unnecessary
	  • If not recently screened, notify patient and offer GC, Ct testing
	  • Do not presumptively treat with topical or oral antibiotics
	• If unexplained inflammation, repeat cytology in one year or sooner
	• If *persistent unexplained* inflammation, some experts recommend colposcopy

Reactive changes associated with intrauterine contraception	• No action is necessary • Patient notification is unnecessary • Repeat cytology at scheduled screening interval
Atrophy	• No action is necessary • Patient notification is unnecessary • Repeat cytology at scheduled screening interval
Endometrial cells in women 40 years of age or older	• Review medical record; if regular menstrual cycles, no action is necessary • If irregular cycles and chronic anovulation suspected, notify and offer (or refer for) endometrial biopsy (Family PACT benefit in this context) • Repeat cytology at scheduled screening interval

Family PACT Abnormal Pap Smear Guidelines

Adapted from: American Society for Colposcopy and Cervical Pathology (ASCCP) 2001 Consensus Guidelines for Management of Women with Cervical Cytological Abnormalities,[1] ASCCP 2001 Consensus Guidelines for the Management of Women with Cervical Intraepithelial Neoplasia,[2] and American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin: Management of Abnormal Cervical Cytology and Histology[3] (2005).

	Initial Intervention	Management of Initial Findings	Subsequent Follow up
ASC-US	**Either:** Repeat cytology at 6 months ***Preferred for adolescents***	• Negative: repeat cytology at 6 mos → • ≥ASC-US: colposcopy	• Negative: routine cytology • ≥ASC-US: colposcopy
	Or: HPV DNA testing (reflex test)	• Negative: repeat cytology at 12 mos → • Positive: colposcopy (in adolescent, may manage as LSIL/adolescent, below)	• Negative: routine cytology • ≥ASC-US: colposcopy
	Or: Colposcopy	• No CIN, HPV pos: cytology at 6 and 12 mos **or** HPV testing at 12 mos → • No CIN, HPV neg: cytology at 12 mos CIN: per ASCCP CIN guideline[2] →	• Negative: routine cytology • ≥ ASC-US or HPV (+): repeat colposcopy
ASC-US postmenopause *(Postmenopausal women are not eligible for Family PACT)*	**Either:** Colposcopy or HPV DNA testing	• Per management of ASC-US	
	Or: Intravaginal estrogen for 4-6 weeks, then repeat cytology	• Negative: repeat cytology at 4-6 mos → • ≥ASC: colposcopy	• Negative: routine cytology • ≥ASC-US: colposcopy
ASC-H	Colposcopy (with ECS)	• No CIN: cytology at 6 and 12 mos **or** HPV testing at 12 mos → • CIN/cancer: per ASCCP CIN guideline[2]	• Negative: routine cytology • ≥ASC-US or HPV (+): colposcopy
LSIL	Colposcopy	• No CIN: cytology at 6 and 12 mos **or** HPV testing at 12 mos → • CIN/cancer: per ASCCP CIN guideline[2]	• Negative: routine cytology • ≥ASC-US or HPV (+): colposcopy
LSIL postmenopause *(Postmenopausal women are not eligible for Family PACT*)	**Either:** HPV DNA at 12 mos	• Negative: repeat cytology at 12 mos → • Positive: colposcopy	• Negative: routine cytology • ≥ASC-US: colposcopy
	Or: Repeat cytology at 4-6 mos	• Negative: repeat cytology at 4-6 mos → • ≥ASC-US: colposcopy	• Negative: routine cytology • ≥ASC-US: colposcopy
	Or: Vaginal estrogen for 4-6 weeks, then repeat Pap	• Negative: repeat cytology at 4-6 mos → • ≥ASC-US: colposcopy	• Negative: routine cytology • ≥ASC-US: colposcopy
LSIL adolescent	**Either:** Cytology at 6 mos ***Preferred***	• Negative: repeat cytology at 6 mos → • ≥ASC-US: colposcopy	• Negative: routine cytology • ≥ASC-US: colposcopy
	Or: HPV DNA at 12 mo	• Negative: repeat cytology at 12 mos → • Positive: colposcopy	• Negative: routine cytology • ≥ASC-US: colposcopy
	Or: Colposcopy	• Per management of LSIL	

HSIL	Colposcopy
	(with ECS)
		• See and treat LEEP (if CIN 2 or 3 likely)
		• Unsatisfactory colposcopy:
		  • CIN biopsy: per ASCCP CIN guideline[2]
		  • No lesion*: DEP
		• Satisfactory colposcopy:
		  • CIN 2/3 biopsy: per ASCCP CIN guideline[2]
		  • No CIN or CIN 1* bx: DEP
			See and treat LEEP is not Family PACT benefit
			
			NOTE: if HSIL cytology and no cervical lesion seen at colposcopy, perform endocervical sampling and evaluate vagina with Lugol's solution for vaginal intraepithelial neoplasia (VaIN)

AGC: Atypical endometrial cells	Endometrial sampling	• Negative endometrial sampling: colposcopy + ECS	

AGC
All other sub-categories
	Colposcopy + ECS
	And:
	Endometrial sampling (if ≥35 years old or abnormal bleeding)
		• Invasive cancer: refer to specialist
		• Pap= AGC-favor neoplasia or AIS: DEP
		• Pap= AGC –not specified (NOS):
		  • Bx= CIN/ AIS: per ASCCP guideline[2]
		  • No CIN/AIS: cytology at 4-6 month intervals **four times** →
			• All 4 negative: routine cytology
			• ASC or LSIL: repeat colposcopy
			• HSIL or AGC: DEP

*** After pathologist review of material, including referral cytology, colposcopic findings, and all biopsies**

ECS= endocervical sampling with endocervical curettage or cervical brush

DEP= diagnostic excisional procedure, e.g., LEEP cone, (cold-knife) cone biopsy, or laser cone biopsy (not Family PACT benefits)